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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,185	12/14/2000	Danny Charles Bowman	2552-011	9139

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EXAMINER
GAKH, YELENA G

ART UNIT	PAPER NUMBER
1743	3

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

mk-3

Office Action Summary	Application No.	Applicant(s)	
	09/737,185	BOWMAN ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication app ars on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *22-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 27-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 December 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-21, drawn to a collection container with a wireless electronic memory tag on a, classified in class 422, subclass 102.

   II. Claims 22-37, drawn to a method for managing the gathering of specimens, classified in class 705, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used for collecting species on site, without any use of the method steps recited in claims 22-37, such as gathering the specimens from the specimen collection sites according to the schedule and route and delivering the specimens to the reference laboratory.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Howard A. MacCord on 01/08/03 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-21 and 27-37. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The independent claims 1, 8, 9, 17 recite a container and a vessel, which makes it unclear, if these are two different containers, with the vessel being enclosed in the container, or this is actually the same container. It is not clear, if this should be a diagnostic specimen **system**, rather than the container, that comprises a collection vessel and a tag.

In claim 4 it is not clear, if "an identifying bar code" corresponds to "an identification code" for the container, or it is a different code. If this is a different code, then it is not clear, what does it identify?

In claim 5 it is not clear, who is "the supplier of the container"? Is this a manufacturer of the container or the collecting laboratory? What particular information is meant by the "product information", and what is mean by the product here – the container? Such language renders the claim unclear and indefinite. To examine the claim on merits the examiner interprets the claim as reciting the "manufacturer of the container" and the "product code".

4. Claims 1-21 and 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: relation between a container, a collection vessel and a wireless electronic memory tag.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 6-7, 9-10, 14-15, 18-19 and 21** are rejected under 35 U.S.C. 102(b) as being anticipated by Berney (US 5,777,303).

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "FIG. 5 shows an exemplary configuration of an electronic label 50 being accessible via radiofrequencies (RF) and which can be used within the scope of the invention. As distinct from the preceding figures, which described devices using labels with contacts, it is of course also possible to use other kinds of electronic labels, **especially labels being read from distance**. This is the case for radiofrequency labels, which use a magnetic coupling" (col. 3, lines 26-33). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2). "FIG. 4 shows an exemplary embodiment of means for reading/writing of a plurality of test tubes 40, 41, 42, 43 and 44 being equipped with electronic labels mounted on their supports. ... It is therefore possible, to control the entirety of the operations relating to the reading and to the transfer of information within the labels under concern with the aid of the keyboard 48 and via computer program menus, allowing to reduce error risks to a minimum. In order to perform, for example, a blood analysis, firstly the reference data of the patient under concern and the kind and number of analyses to be performed are fed directly from a central database into the label. Secondly the date of analysis, the used analysis apparatus, the name of the service operator, the result data, etc are registered. Finally all this information is transferred to the centralized data bank of the patient" (col. 2, lines 66-67 and col. 3, lines 1-25). There are no structural differences between "a diagnostic specimen container" and "a toxicology specimen container" the way they are recited in the claims indicated above.

The methods for electronically storing information and recording information, recited in claims 18, 19 and 21 are inherently disclosed in the specification.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of disclosure of RD 421048 A.

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be

self-powered or passive **transponder** type". "The ID tag with each container individualizes the solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

It would have been obvious for anyone of ordinary skills in the art to use a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, in Berney's specimen container, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A and because this is one of "other kinds of electronic labels, especially labels being read from distance", mentioned by Berney.

11. **Claims 3-4 and 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Stevens et al. (EP 1,004,359 A2).

Berney does not specifically disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

It would have been obvious for anyone of ordinary skills in the art to improve Berney's container comprising the electronic tag by adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container.

12. **Claims 5 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Stevens, as applied to claims 3 and 4 above, and further in view of the prior art disclosed by Leuenberger (US 5,314,421).

Although Stevens indicated that the label may contain product information, he is silent regarding information on a supplier.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to include information on the product supplier in the electronic tag the same way as indicated by Leuenberger for blood packs, because containers from different suppliers may vary, and therefore such information is important for handling containers properly, and because information on a supplier is always conventionally provided with products.

13. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens and Leuenberger.

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2).

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the

solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

Berney and RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

Berney, RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

It would have been obvious for anyone of ordinary skills in the art to modify Berney's container by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A; adding a label with a barcode and providing the same information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container; and adding information on identity of suppliers as indicated by Leuenberger, because,

first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container.

14. **Claims 16 and 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of Fukuzaki (US 5,948,103).

Berney does not disclose an encoded electronic signature of a donor of a toxicological specimen stored in the tag.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skills in the art to employ Fukuzaki's electronic security system, including encoded electronic signature security system, for Berney's container when it is used for toxicological analysis, because the information contained in Berney's electronic label should be secured in the case of toxicological analysis, and Fukuzaki provides the most convenient way of securing the information with the encoded electronic signature, which should be the donor's electronic signature in this case.

15. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Berney in view of RD 421048 A, Stevens, Leuenberger, Fukuzaki and Coli et al. (US 6,018,713).

Berney discloses a diagnostic specimen container comprising a biomedical specimen collection vessel (a test tube) and a wireless electronic memory tag for non-contact storage and retrieval of information (Abstract, Figure 5). "Said electronic label 4 allows a registration of all useful information required for said analysis, in particular, information relating to the person under concern, to basis reference data, to the analysis data and to the result data, to the used analysis apparatus, to the service staff, etc." (col. 1, lines 61-67, col. 2, lines 1-2).

Berney does not specifically disclose a radio frequency transponder, although he mentions that "it is of course also possible to use other kinds of electronic labels, especially labels being read from distance. This is the case for radiofrequency labels".

RD 421048 A discloses a "method for logging, identification, tracking, and chemical management in a chemical synthesis system (CSS) – by applying an electronic identification tag to each container as it passes through the system" (Title). "The identification (ID) tags could be self-powered or passive **transponder** type". "The ID tag with each container individualizes the

solvents, reagents, intermediates and finished compounds within the CSS" (Abstract). "A complete and accurate log of every container transport and access can be maintained. ... Chain of custody with ID labeling is excellent" (Advantage).

Berney and RD 421048 A do not disclose a container, which further includes a label imprinted with an identifying barcode and the electronic tag of which stores data including an identification code for the container.

Stevens discloses a partitioned specimen label for collection containers, which comprises "a machine readable barcode identification and a portion of the label and barcode can be removed from the container and subsequently affixed to test request forms and the like. The label of the present invention is able to create a direct link between the container, the patient and the test request forms" (col. 2, paragraph [0013]). In one of the embodiments, "the first two of the digits [of the barcode] are fixed and identify the tube and product type for features such as but not limited to tube size, tube material and internal additives" (col. 4, l. 58 and col. 5, ll. 1-2).

Berney-RD 421048 A and Stevens do not specifically indicate that the tag contains information on the supplier.

Leuenberger in his "Background of the Invention" related to the blood pack labels indicates, concerning blood plastic containers, "of course, it is necessary to provide some means for identifying certain information on the blood pack, e.g., the type of storage solution, anticoagulant, or blood component, the collection date, manufacturer's product code and lot number, etc." (col. 1, lines 13-18).

Berney, RD 421048 A, Stevens and Leuenberger do not disclose encoded electronic signature of the donor stored in the electronic tag.

Fukuzaki discloses an electronic document security system, affixed electronic seal security system and encoded electronic signature security system for securing electronic documents transmitted by electronic means.

It would have been obvious for anyone of ordinary skills in the art to modify Berney's container by introducing a radio-frequency transponder in the electronic memory tag, disclosed in RD 421048 A, because transponder gives more flexibility in "logging, identification, tracking and chemical management" of the container due to the long-range action of the transponder, as demonstrated in RD 421048 A; adding a label with a barcode and providing the same

information to the electronic tag in the same way Stevens labeled his container, because this serves the same purpose that Stevens disclosed in his invention, i.e. to "create a link between the container, the patient and the test request forms", or any other forms associated with using this container; adding information on identity of suppliers as indicated by Leuenberger, because, first this is a conventional information always provided with the products, and second, because the identity of the supplier may assist in the proper handling the container; and adding an encoded electronic signature of the donor of the toxicological specimen, because the information contained in improved Berney's electronic label should be secured in the case of toxicological analysis, and Fukuzaki provides the most convenient way of securing the information with the encoded electronic signature, which should be the donor's electronic signature in this case.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Raj (US 5,008,661)* discloses electronic remote chemical identification system, comprising a transponder for remotely recording information on the content of chemical containers. *Gorman (US 5,272,318)* discloses electronically readable locking system, which requires scanning of identification means associated with a patient and proposed treatment. *Kouch et a. (US 5,541,394)* disclose a delivery management system utilizing a two-dimensional bar code having key information for specifying the source of a material and its content information, including a case for chemical materials. *Domanik et al. (US 5,963,368)* disclose a system for managing specimens in a clinical laboratory. *Medeiros et al. (US 5,831,859)* disclose a pharmaceutical recodkeeping system with labeling for manufacturing raw materials. *Marchonsky (US 2002/0029157 A1)* discloses patient-controlled automated medical record, diagnosis, and treatment system and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 10:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-7165 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Yelena G. Gakh
January 10, 2003